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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,337	02/19/2004	Hector F. DeLuca	1256-00931	5401

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EXAMINER	
QAZI, SABIHA NAIM	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,337	DELUCA ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Non-Final Office Action

Claims 1-67 are pending. No claim is allowed at this time. Acknowledgement is made of the response filed on 6/5/2006. Previous rejections are maintained and new rejection are being made.

Summary of this Office Action dated Tuesday, August 15, 2006

1. Response to Remarks
2. Information Disclosure Statement
3. Copending Applications
4. Specification
5. 35 USC § 112 --- First Paragraph Written description Rejection
6. 35 USC § 112 --- First Paragraph Scope of Enablement Rejection
7. Double Patenting
8. 35 USC § 102(e) Rejection
9. 35 USC § 103(a) Rejection
10. Communication

Response to Remarks

- Examiner thanks Dr. Wozny for his cooperation.
- Arguments made in currently filed remarks and previous filed remarks has been considered. Examiner understands the teachings of RIGGS, SARKAR and KLEEREKOPER references cited by the Applicants. These references were very helpful in understanding about various types of fractures, BMD and various other issues related to present application.
- Applicants need to explain more about certain claims as claim 26 and various other claims how 2MD can prevent the fracture, as claimed for method for prophylaxis of a disease characterized by a need to increase the strength of a bone method of "prophylaxis of a disease characterized by a need to increase the strength of a bone", how method of increasing bone strength can be predicted. Where is the guidance how to prevent development of or delaying of a disease by increasing strength of bone (claim 26). Furthermore, claims are drawn to prevent bone fractures (claim 44) as well as a method of prophylaxis of fractures, osteoporosis, increasing eggshell strength of a laying hen, etc. which has not been explained in the disclosure.
- Applicant has explained about their invention it is requested how this invention can be used. If there were any reason one would expect the increase in bone strength and prevent various disorders Applicant should explain more about it.
- In order to advance the prosecution Applicant may consider calling the Examiner to discuss the issues surrounding this application.

Information Disclosure Statement

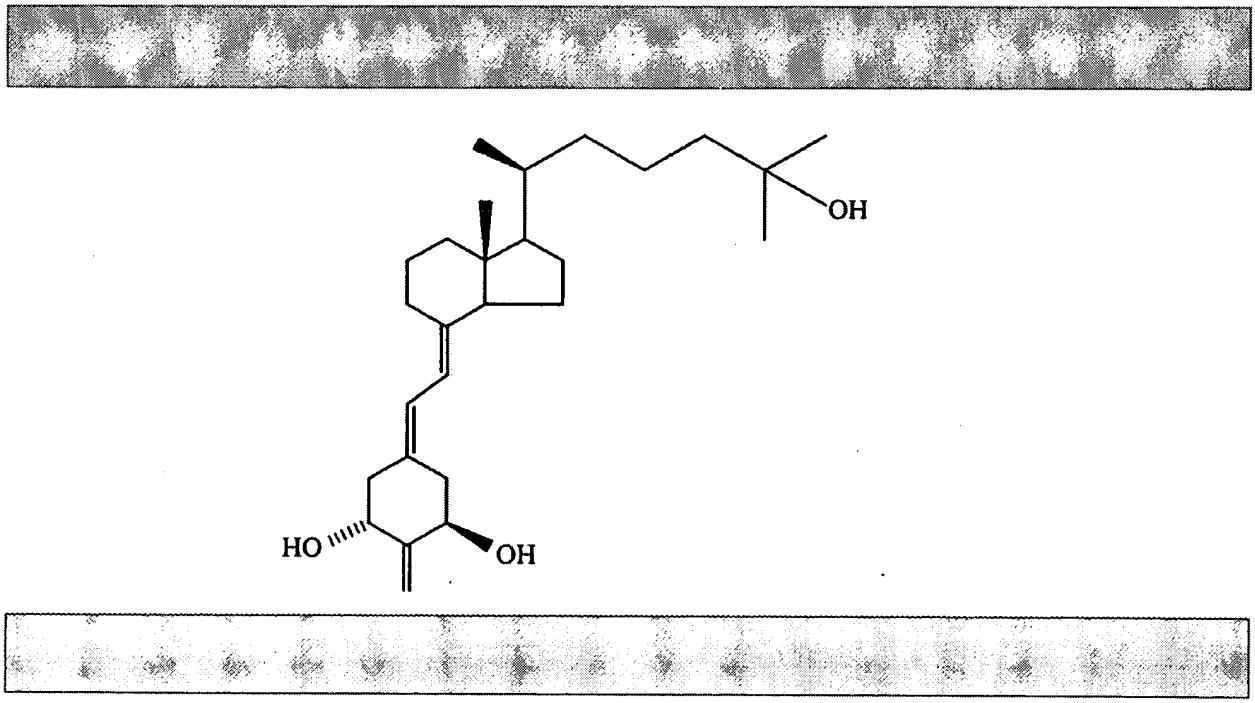
The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.



2-methylene-19-nor-20(S)-1aplha,25-dihydroxy vitamin D_3 (2MD)

Claim Rejections - 35 USC § 112—Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-67 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Presently claimed invention is drawn to method of "prophylaxis of a disease characterized by a need to increase the strength of a bone", preventing development of or delaying onset of a disease where strength of bone is needed as well as a method of prophylaxis of fractures, osteoporosis, increasing eggshell strength of a laying hen, etc.

However, there is no evidence of possession for all the methods as claimed. What is known is known to one skilled in the art need not to be disclosed in detail See *Vas-Cath, Inc. v. Mahurkar*, 935 F 2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).

If technology is less mature, the heavier the burden on the disclosure to demonstrate the possession at the time of effective filing date. In present case claimed methods are drawn to prophylaxis, of a disease where bone strength is need, prevention of fracture, preventing development of or delaying onset of a disease where strength of bone is needed is unpredictable. See *In re Curtis*, 69 USPQ2d 1275 (CAFC 2004), the court held there was sufficient evidence to indicate that ordinary artisans could not predict the operability of other species other than the single one disclosed in the specification. See also Uni. of Rochester v. G. D. Searle 71 USPA2d 1545 (CAFC 2004).

See written description Guidelines (66 FR 1099 (Jan. 5. 2001): 1242 O.G. 168 (Jan. 30. 2001).

35 USC § 112 --- First Paragraph Scope of Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-67 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of osteoporosis, does not reasonably provide enablement for all the methods as claimed, for example method of prophylaxis of a disease characterized by a need to increase bone strength (claim1), method of preventing development of or delaying onset of a disease characterized by a need to increase bone strength, (claim 26) prevention of bone fracture and others as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The claims are drawn to method of prophylaxis where increase the strength of a bone is needed and a method of "prophylaxis of a disease characterized by a need to increase the strength of a bone" method of preventing development of or delaying onset of a disease characterized by a need to increase bone strength as well as a method of prophylaxis of fractures, osteoporosis, increasing eggshell strength of a laying hen, etc.

The predictability or unpredictability of the art: Method of increasing bone strength cannot be predicted. There is no guidance how to prevent development of or delaying of a disease by increasing strength of bone (claim 26). Furthermore, claims are drawn to prevent bone fractures (claim 44).

There is no support in the specification as claimed.

The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) ("Nascent technology, however, must be enabled with a 'specific and useful teaching.' The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology."

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971), stated:

In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof.

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). It is not obvious from the disclosure of one species, what other species will work. See MPEP 2164.03.

The amount of direction or guidance presented: There is no guidance in the disclosure on how to use the invention. The conclusion in the specification (page 20) has been considered. Table 1 on page 17 and Table 2 on page 18 lists some data, however, it is not clear how the bone strength can be achieved for several instances as claimed.

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971).

The quantity of experimentation necessary: Since there is no direction and guidance provided in the specification for presently claimed method of "prophylaxis of a disease characterized by a need to increase the strength of a bone" as well as a method of prophylaxis of fractures, osteoporosis, increasing eggshell strength of a laying hen, etc., one skilled in the art at the time of invention would have to go through undue experimentation to make and use the presently claimed invention.

The first paragraph of 35 USC 112 requires "*...such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains...*" The instant invention fails to meet this requirement, as it lacks such

full, clear, and concise manner as to enable any person skilled in the art to which it pertains to make and/or use the invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-29 of DELUCA et al. (US Patent No. 5843928). Although the conflicting claims are not identical, they are not patentably distinct from each other because US '928 claims 17-29 are drawn to a method of treating metabolic bone disease where it is desired to maintain or increase bone mass by 2-methylene-19-nor-20(S) vitamin D compounds.

Instant claims differ from the reference in claiming a method of "prophylaxis of a disease characterized by a need to increase the strength of a bone" as well as a method of prophylaxis of fractures, osteoporosis, increasing eggshell strength of a laying hen, etc.

It would have been obvious to one skilled in the art at the time of invention to 2MD for the increase of strength of a bone, wherever it may be needed, because the prior art is drawn to the treatment of metabolic bone disease through the increase of strength of a bone.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> *A person shall be entitled to a patent unless –*
>
> *(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.*

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-43 are rejected under 35 U.S.C. 102(e) as being anticipated by DELUCA et al. (US Patent No. 5843928). US '928 claims 17-29 are drawn to a method of treating metabolic bone disease where it is desired to maintain or increase bone mass by 2-methylene-19-nor-20 (S) vitamin D compounds.

Instant claims differ from the reference in claiming a method of "prophylaxis of a disease characterized by a need to increase the strength of a bone" as well as a method of prophylaxis of fractures, osteoporosis, increasing eggshell strength of a laying hen, etc.

Present claims are drawn to the use of 2MD for the increase of strength of a bone, wherever it may be needed, is inherently taught because the prior art is drawn to the treatment of metabolic bone disease through the increase of strength of a bone. The treatment is intended for the same population.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

See Exparte Novitski, 26 USPQ 2d 1389 (January 22, 1993) which is decision of USPTO Board of Appeals, holding to be inherent and not patentable, inoculating healthy plants with a known plant inoculant's, employed in the prior art to protect them against phytopathogenic fungi. Novitski discovered that the known plant inoculants would also protect them against root dwelling plant pathogenic nematodes, a discovery neither known nor appreciated by the prior art. The step of inoculating plants with the same inoculants necessarily and inherently protects them against nematodes.

See Atlas Powder versus Ireco, 51 USPQ 2d 1943, (Fed. Cir. 1999), holds the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition does not render the old composition new to the discoverer.

The fact that prior art taught away from the claim is, in fact, only a showing that prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency.

35 USC § 103(a) Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-67 rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (WO 02/05823). The reference teaches the method of use of 2-methylene-19-nor-20(S)-1aplha,25-dihydroxy vitamin D_3 (2MD) for the treatment of disease where bone strength is desired which embraces Applicant's claimed invention. See the entire document especially lines 5-13 on page 4, line 19 on page 4see lines 3-7 on page 5, see lines 1-13 on page 6, see figures 6a, 6b, 7 and 8.

Instant claims are broader than the prior art. Prior art teaches 2-methylene-19-nor-20(S)-1aplha,25-dihydroxy vitamin D_3 (2MD) useful for treatment of diseases where increase in bone mass is desired , for increase in bone strength (line 4 on page 6 and figure 6b) , restoration of building of bone wherein instant claims are drawn to a method for prophylaxis of a disease characterized by a need to increase the strength of a bone method of "prophylaxis of a disease characterized by a need to increase the strength of a bone" as well as a method of prophylaxis of fractures, osteoporosis, increasing eggshell strength of a laying hen, etc.

It would have been obvious to one skilled in the art to use 2-methylene-19-nor-20(S)-1aplha,25-dihydroxy vitamin D_3 (2MD) when increase in bone strength is needed because prior art teaches the use of this compound for

increase in bone strength. Since there is critical distinguishing criteria has been established the presently claimed invention is considered obvious over the prior art at the time of invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Data in the Specification

The data in the specification has been considered in view of the remarks. Applicants need to explain more about certain claims as claim 26 and other claims how 2MD can prevent the fracture, as claimed for method for prophylaxis of a disease characterized by a need to increase the strength of a bone method of "prophylaxis of a disease characterized by a need to increase the strength of a bone", Method of increasing bone strength cannot be predicted. There is no guidance how to prevent development of or delaying of a disease by increasing strength of bone (claim 26). Furthermore, claims are drawn to prevent bone fractures (claim 44) as well as a method of prophylaxis of fractures, osteoporosis, increasing eggshell strength of a laying hen, etc.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SABIHA QAZI, PH.D
PRIMARY EXAMINER